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Original Research Article

A hospital-based study on the incidence, severity and risk factors of retinopathy of prematurity

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ABSTRACT

Background: Retinopathy of prematurity (ROP) is a leading cause of preventable childhood blindness in India. Improved neonatal survival has increased its incidence, necessitating region specific data on risk factors and disease severity in Western Maharashtra. Objectives of the study were to determine the incidence and severity of ROP and identify associated maternal and neonatal risk factors in a hospital setting.
Methods: A cross-sectional study was conducted on 86 preterm infants (<34 weeks or <2000g) admitted to a NICU in Kolhapur. Infants were screened for ROP by a paediatric ophthalmologist using Retcam or indirect ophthalmoscopy. Demographic, clinical, and risk factor data were collected. Statistical analysis was performed using statistical package for the social sciences (SPSS) to compare variables between severe and non-severe ROP groups.
Results: Out of 86 newborns screened, 23 developed ROP. Incidence of ROP was 26.7%. Among 23 neonates with ROP, the majority (47.8%) were born at 31–32 weeks gestation and 56.5% weighed 1–1.5 kg. Stage 1 ROP was most common (47.8%). Severe ROP was present in 39.1% of cases. Birth weight <1 kg (p=0.049) and need for mechanical ventilation (p=0.021) were significantly associated with severe ROP. The mean duration of oxygen therapy was significantly longer in the severe group (22.44 versus 13.93 days, p=0.043). A high prevalence of anaemia (78.3%) and sepsis (82.6%) was observed, though not statistically significant for severity.
Conclusion: Low birth weight, prolonged oxygen therapy, and mechanical ventilation are significant risk factors for severe ROP. Targeted screening and optimized neonatal care are essential to reduce vision-threatening ROP.

Keywords: Retinopathy of prematurity, Incidence, Risk factors, Preterm infants, Mechanical ventilation

INTRODUCTION

Retinopathy of prematurity (ROP) remains one of the leading but avoidable cause of childhood blindness in developing countries, especially in India, where improved neonatal survival has heightened its clinical significance. In western India, a hospital-based prospective study of neonates <34 weeks' gestation and/or <1700 g birth weight reported an ROP incidence of 19.3%, with severe ROP in 10.3%. Oxygen therapy increased odds of any ROP nearly threefold and severe ROP sevenfold.[1] In a tertiary centre in Aurangabad, Maharashtra, among 150 preterm infants screened, ROP was seen in 47%, with statistically significant associations for oxygen use >2 days, sepsis, intraventricular hemorrhage, blood transfusion, and respiratory distress syndrome.[2]

State-level data suggest that in Maharashtra, approximately 20% of preterm survivors develop ROP and 5% risk vision-threatening ROP, underscoring urgent public health needs.[3] Nationwide data reinforce that ROP incidence ranges from about 21% to over 50 % among low-birth-weight infants, with low gestational age, oxygen supplementation, sepsis, and blood transfusions consistently identified as key risk factors.[4,5] The broader pathophysiology of ROP involves disrupted retinal vascular development triggered by hyperoxia and hypoxia-

especially in preterm, low-birth-weight neonates-leading to aberrant neovascularization and retinal detachment.[6]

Though screening protocols exist, their inconsistent application in India, and the evolving epidemiology driven by improved neonatal care, prompt further region-specific investigation.[7,8] Western Maharashtra, with its varied neonatal care settings, remains underrepresented in ROP epidemiology literature despite being demographically significant. Given this context, a well-designed, hospital-based study focusing on incidence, severity, and risk factors of ROP in western Maharashtra would fill a critical knowledge gap, inform screening strategy, and guide resource allocation.

This study addresses an urgent gap: accurate, region-specific ROP epidemiology for western Maharashtra. By quantifying incidence, severity, and modifiable risk factors, it enables tailored screening protocols, early intervention strategies, and health-policy planning to reduce the burden of ROP-related childhood blindness in a high-risk population.

METHODS

The present cross-sectional study was conducted after approval from Intuitional Ethics Committee. A total of 86 preterm infants admitted to the NICU of Department of Pediatrics at CPR Hospital, Kolhapur, Maharashtra, were included. Infants born with a gestational age below 34 weeks or with birth weight under 2000 g, presented any risk factors such as respiratory distress syndrome, exposure to prolonged oxygen therapy, sepsis, intraventricular hemorrhage, or history of blood transfusion. Infants with major congenital anomalies, chromosomal abnormalities, or inborn errors of metabolism were excluded, as were those whose parents declined participation or were lost to follow-up.

Once eligibility was confirmed, detailed neonatal and maternal data—including gestational age, birth weight, sex, oxygen supplementation and its duration, need for mechanical ventilation, sepsis, intraventricular hemorrhage, blood transfusions and anemia were systematically recorded in structured pro-forma. Gestational age was determined using a combination of first-trimester ultrasound and New Ballard scoring. All enrolled infants underwent retinal screening for ROP by a qualified pediatric ophthalmologist using Retcam or indirect ophthalmoscopy to determine zone, stage, extent (clock hours), and plus disease. Screening was first conducted at 4 weeks postnatally (or around 3 weeks for extremely preterm or very low–birth-weight infants), with repeat examinations every two weeks until full retinal vascularization was attained.

Out of total 86 preterm infants screened, 23 developed ROP. They were identified and formed our study cohort. Incidence of ROP was found to be 26.7% (23/86). To compared risk factors, patients were categorized into non-severe ROP (comprising stages 1, 2, and stage 3 below treatment threshold) and severe ROP, presumably including threshold disease, plus disease, and/or stages warranting intervention (laser or anti-VEGF). All clinical variables and maternal/neonatal risk factors were captured prospectively from admission through follow-up. The primary outcomes assessed were incidence and severity of ROP. Secondary outcomes included identification of risk factors associated with progression to severe ROP.

Statistical analysis was conducted using appropriate software statistical package for the social sciences (SPSS). Continuous variables were compared using student's t-test, while categorical variables were tested by Chi-square or Fisher's exact test. Univariate analysis identified candidate risk factors, and significant ones were entered into a multivariate logistic regression model to determine independent predictors of severe ROP.

RESULTS

Incidence of retinopathy of prematurity

Out of total 86 preterm infants screened, incidence of Retinopathy of prematurity (ROP) was 23/86 (26.7%) (Figure 1).

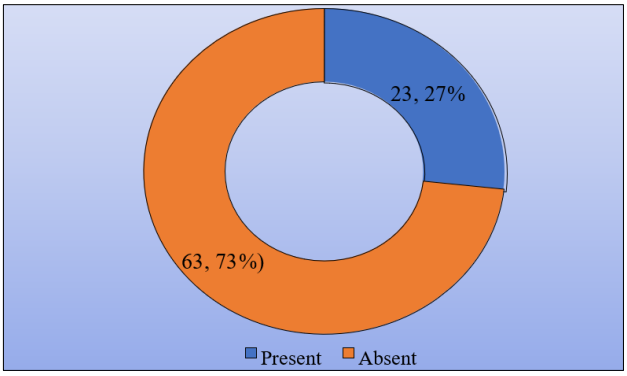

Figure 1: Incidence of retinopathy of prematurity.

Demographic and clinical profile of the neonates

In the present study, out of 23 neonates with ROP, the majority of neonates were born between 31–32 weeks (47.8%), followed by 33–34 weeks (39.1%). A smaller proportion were extremely preterm at 28–30 weeks (8.7%), while only one neonate (4.3%) was ≥35 weeks. Most neonates weighed 1–1.5 kg (56.5%), while 34.8% had weights between 1.6–2.0 kg. Only 8.7% had extremely low birth weight (<1 kg).

Almost half of the neonates (47.8%) required mechanical ventilation, while 52.2% did not. 17.4% were twins, and the remaining 82.6% were singleton births. A high prevalence of anemia was noted, with 78.3% neonates affected, compared to only 21.7% without anemia. More than half (52.2%) received at least one blood transfusion. Five neonates (21.7%) required two transfusions, and one

neonate (4.3%) needed four transfusions. Another 21.7% did not require transfusion. Positive blood culture indicating sepsis was found in 82.6%, while only 17.4% had no growth. *Klebsiella* in 21.7%, *Acinetobacter* in 13.0% and *Candida* in 17.4%.

Coagulase negative *Staphylococcus* (CONS) was observed in 13%, CONS with Candida and Klebsiella with *Citrobacter* were observed in 4.3% each (Table 1).

Table 1: Demographic and clinical profile of the neonates.

Demographic profile	Frequency	Percent (%)
Gestational age (weeks)		
28-30	2	8.7
31-32	11	47.8
33-34	9	39.1
≥35	1	4.3
Weight of the neonates (kgs)		
<1	2	8.7
1-1.5	13	56.5
1.6-2	8	34.8
Need for mechanical ventilation		
Yes	11	47.8
No	12	52.2
Twins		
Yes	4	17.4
No	19	82.6
Anemia		
Yes	18	78.3
No	5	21.7
Blood transfusion		
1 received	12	52.2
2 received	5	21.7
4 received	1	4.3
No	5	21.7
Blood culture		
Growth	19	82.6
No growth	4	17.4
Need of inotropes		
Yes	21	91.3
No	2	8.7
Total	23	100.0

The majority (91.3%) required inotropic support, whereas only 8.7% did not. Most neonates with ROP were preterm (≤34 weeks), low birth weight (≤1.5 kg), anaemic, septic, and hemodynamically unstable, with a significant proportion requiring transfusions, inotropes, and ventilatory support—all of which are known risk factors for ROP.

Stage of retinopathy of prematurity

Among the 23 neonates, the majority were in the early stages of the disease. Stage 0, representing incomplete vascularization, observed in 3 (13%) neonates, while stage 1, was the most common, affecting 11 (47.8%) neonates. Stage 2, was noted in 5 (21.7%) neonates, whereas Stage 3 was present in 2 (8.7%) neonates. In addition, aggressive posterior ROP (APROP), was identified in 2 (8.7%) neonates. Overall, nearly two-thirds of the cohort (stages 0 and 1) had mild forms of ROP, while a smaller proportion (stages 3 and AP-ROP) demonstrated advanced, disease (Figure 2).

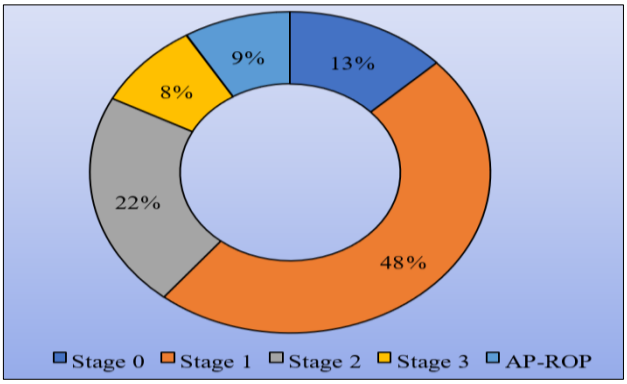

Figure 2: Stages of ROP.

Among the 23 neonates with ROP, 9 (39.1%) developed severe disease while 14 (60.9%) had non-severe forms. Gestational age did not show a statistically significant association with severity (p=0.788), although half of the neonates born at 28–30 weeks progressed to severe ROP. Birth weight, however, was significantly associated with severity (p=0.049); all neonates weighing <1 kg developed severe ROP, while those between 1.6–2.0 kg had the lowest proportion of severe disease (12.5%). The need for mechanical ventilation also demonstrated a significant association (p=0.021), with 63.6% of ventilated neonates developing severe ROP compared to only 16.7% among those not requiring ventilation. Other factors such as twin gestation (75% versus 31.6%, p=0.106), anemia (44.4% versus 20.0%, p=0.322), positive blood culture (42.1% versus 25.0%, p=0.524), and inotropic support (38.1% versus 50.0%, p=0.640) did not reach statistical significance, though trends toward higher severity were observed in twins, anemic neonates, and those with sepsis (Table 2).

Comparison of mean duration of oxygen requirement (days) between severe and non-severe ROP

The mean duration of oxygen requirement was significantly longer in neonates who developed severe ROP compared to those with non-severe disease (22.44±8.19 days versus 13.93±9.83 days, p=0.043) (Figure 3).

Table 2: Association between risk factors and severity of ROP.

Demographic profile	Severe / no-severe ROP		Total (%)	P value
	Non-severe (%)	Severe (%)		
Gestational age (weeks)				
28-30 years	1 (50.0)	1 (50.0)	2 (100.0)	0.788
31-32	6 (54.5)	5 (45.5)	11 (100.0)	
33-34	6 (66.7)	3 (33.3)	9 (100.0)	
≥35	1 (100.0)	0 (0.0)	1 (100.0)	
Weight of the neonate (Kgs)				
<1	0 (0.0)	2 (100.0)	2 (100.0)	0.049
1-1.5	7 (53.8)	6 (46.2)	13 (100.0)	
1.6-2	7 (87.5)	1 (12.5)	8 (100.0)	
Need for mechanical ventilation				
Yes	4 (36.4)	7 (63.6)	11 (100.0)	0.021
No	10 (83.3)	2 (16.7)	12 (100.0)	
Twins				
Yes	1 (25.0)	3 (75.0)	4 (100.0)	0.106
No	13 (68.4)	6 (31.6)	19 (100.0)	
Anemia				
Yes	10 (55.6)	8 (44.4)	18 (100.0)	0.322
No	4 (80.0)	1 (20.0)	5 (100.0)	
Blood culture				
Growth	11 (57.9)	8 (42.1)	19 (100.0)	0.524
No growth	3 (75.0)	1 (25.0)	4 (100.0)	
Inotropic support				
Yes	13 (61.9)	8 (38.1)	21 (100.0)	0.640
No	1 (50.0)	1 (50.0)	2 (100.0)	
Total	14 (60.9)	9 (39.1)	23 (100.0)	

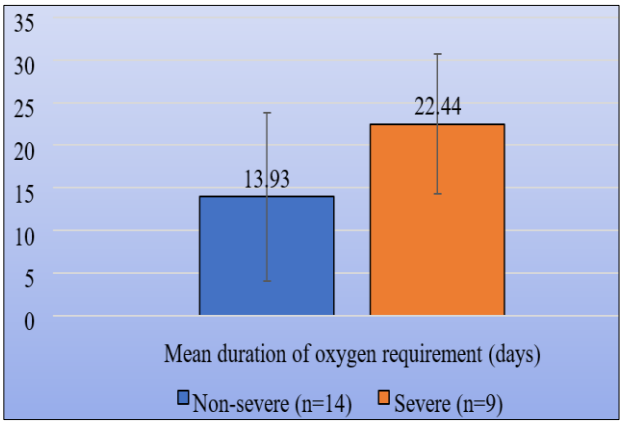

Figure 3: Comparison of mean duration of oxygen requirement (days) between severe and non-severe ROP.

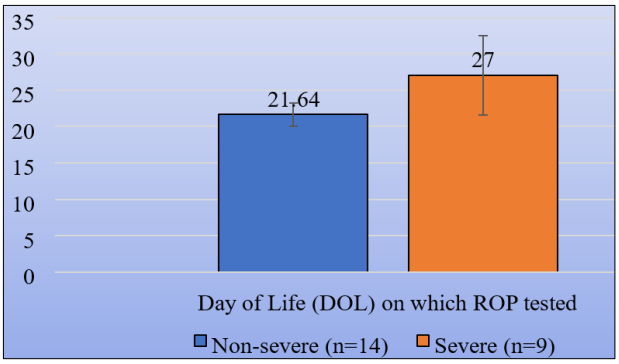

Figure 4: Comparison of mean day of life (DOL) on which ROP tested between severe and non-severe ROP.

Comparison of mean day of life (DOL) on which ROP tested between severe and non-severe ROP

Similarly, the mean day of life (DOL) on which ROP was detected was significantly later in the severe group (27±5.45 days) compared to the non-severe group (21.64±1.55 days), with a highly significant difference (p=0.002) (Figure 4).

DISCUSSION

Incidence of retinopathy of prematurity

Incidence of retinopathy of prematurity in our study was 26.7%, which is compared to other studies done in other parts of India. Chaudhari et al reported incidence of 22.3%, Gupta et al 21.7% and Sanghi et al reported 21.8% which were comparable with our study.[9-11] There is need to emphasize more on timely screening for retinopathy of prematurity and need to strengthen the screening

programme for retinopathy of maturity by organizing camps at grass root level.

Gestational age distribution and ROP development

Our study revealed that the majority of ROP cases occurred in infants born at 31-32 weeks gestation (47.8%), followed by 33-34 weeks (39.1%). This distribution is consistent with recent studies, although with some variation in proportions. A multi-center Pakistani study by Shehadeh et al reported that among 350 infants screened, the mean gestational age of ROP-positive cases was 29.2 weeks, with an overall ROP incidence of 5.1%.[12] Similarly, an Iranian study by Maleki et al found that among 920 screened infants, those with ROP had significantly lower mean gestational age (27.7 weeks) compared to those without ROP (28.9 weeks).[13] In contrast, a recent study from Vienna by Blazon et al reported that infants with ROP had a mean gestational age of 25.9 weeks compared to 28.9 weeks in those without ROP.[14]

Birth weight as a critical risk factor

Our findings demonstrate a significant association between birth weight and ROP severity, with all neonates weighing less than 1 kg developing severe ROP (p=0.049). This finding is remarkably consistent with international literature. The Iranian study by Naghshineh et al showed that infants with ROP had significantly lower mean birth weight (778.6 grams) compared to those without ROP (1134.9 grams).[13] A recent Central Indian study by Kumar et al found that 33 out of 40 ROP cases (82.5%) occurred in neonates with birth weight ≤2 kg, with an incidence rate of 18.9% in this weight category.[15] The consistency of these findings across different populations underscores the universal nature of birth weight as a fundamental risk factor for ROP development.

Mechanical ventilation and respiratory support

Our study found that mechanical ventilation was significantly associated with severe ROP, with 63.6% of ventilated neonates developing severe disease compared to 16.7% of nonventilated infants (p=0.021). This finding aligns closely with recent research demonstrating the critical role of respiratory support in ROP pathogenesis. A Spanish study by Arnaiz-García et al developed a predictive model showing that each additional day of mechanical ventilation increased the odds of requiring ROP treatment (OR 1.05, 95% CI 1.02-1.09).[16]

The Portuguese multi-centre study by Santos et al identified mechanical ventilation as a significant risk factor in multivariate analysis, particularly highlighting the duration and intensity of respiratory support.[17] These findings suggest that not only the need for mechanical ventilation but also its duration plays a crucial role in ROP development.

Oxygen therapy duration and ROP severity

Our study revealed that the mean duration of oxygen requirement was significantly longer in severe ROP cases (22.44±8.19 days versus 13.93±9.83 days, p=0.043). This finding is strongly supported by recent literature emphasizing the critical period of oxygen exposure. A study by Singh et al found that 85% of infants with severe ROP received oxygen therapy for more than seven days.[18] The relationship between oxygen duration and ROP severity has been consistently demonstrated across multiple recent studies. A systematic review by Kim et al noted that prolonged oxygen therapy remains one of the most frequently identified risk factors for severe ROP requiring treatment.[19] The mechanism involves the disruption of normal retinal vascular development through hyperoxia-induced vasoconstriction followed by subsequent hypoxia-driven pathological neovascularization.

Sepsis and systemic inflammation

Our study found that 82.6% of ROP cases had positive blood cultures, indicating a strong association between sepsis and ROP development. Recent meta-analyses have consistently supported this association. A comprehensive systematic review by Huang et al including 34 studies demonstrated that sepsis significantly increased the risk for any stage ROP (OR 2.16, 95% CI 1.65-2.82), with both early-onset (OR 2.50) and late-onset sepsis (OR 1.37) associated with severe ROP.[20]

A recent Iranian study by Boskabadi et al compared 155 preterm infants with sepsis to 145 controls, finding ROP incidence of 70% in the sepsis group versus 58% in controls (p=0.023).[21] Recent research by Joshi et al noted that sepsis was prevalent in 70% of infants with severe ROP, emphasizing the need for stringent infection control measures in NICUs.[18]

Anemia and blood transfusion patterns

Our study demonstrated that 78.3% of ROP cases had anemia, with over half requiring blood transfusions. Recent research has revealed complex relationships between anemia, blood transfusions, and ROP development. A prospective multicenter Chinese study by Wang et al found that red blood cell transfusion within the first 4 weeks significantly increased ROP risk, with the association remaining consistent across different gestational age groups.[22] The study noted that 60.7% of preterm infants ≤32 weeks received at least one transfusion.

A recent narrative review by Prasad et al highlighted that while anemia itself may be protective through reduced oxygen delivery, the correction of anemia through transfusion may paradoxically increase ROP risk through tissue hyperoxia.[23] These findings suggest that transfusion

strategies require careful consideration, balancing the need to correct anemia against potential ROP risk.

ROP stage distribution and severity

Our study showed that stage 1 ROP was most common (47.8%), followed by stage 2 (21.7%), with 39.1% developing severe disease. Recent international data shows considerable variation in stage distribution. The Austrian study by Blazon et al found stage 2 as the most common severity in 51.4% of cases, with 40.9% overall ROP incidence but only 4.8% requiring treatment.[14] A Portuguese study by Fevereiro-Martins et al reported 37.8% ROP incidence with 4.6% requiring treatment.[17] These variations likely reflect differences in overall infant survival rates, screening criteria, and healthcare infrastructure.

Limitations

While our findings contribute valuable insights to the understanding of ROP risk factors, several limitations should be acknowledged. The relatively small sample size of 23 neonates may limit the generalizability of our findings. Additionally, the hospital-based nature of our study may introduce selection bias toward more severe cases.

CONCLUSION

In the present study, incidence of ROP was 26.7% and nearly 40% of affected neonates developed severe disease. Low birth weight, prolonged oxygen requirement, and mechanical ventilation show significant associations with severity, while anemia, sepsis, and multiple births contribute as potential risk factors. The findings highlight that preterm, low-birth-weight infants exposed to intensive respiratory support remain most vulnerable.

Early screening and risk-based monitoring are crucial to prevent progression to sight threatening ROP. Routine and timely ROP screening should be implemented for all preterm and low-birth-weight infants. Strict oxygen monitoring, judicious transfusion practices, infection control, and multidisciplinary neonatal care are recommended to reduce ROP incidence and severity, thereby preventing avoidable childhood blindness.

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